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10/010,709	11/05/2001	A. Gururaj Rao	0233C3	7017

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EXAMINER

KUBELIK, ANNE R

ART UNIT	PAPER NUMBER
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1638

DATE MAILED: 03/16/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

10/010,709

Applicant(s)

RAO ET AL.

Examiner

Anne R. Kubelik

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-21 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 1, 7, 10 and 16 is/are allowed.
- 6) ☒ Claim(s) 5, 6, 15, 20 and 21 is/are rejected.
- 7) ☒ Claim(s) 2-4, 8, 9, 11-14 and 17-19 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 05 November 2001 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.  
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

### Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

### DETAILED ACTION

1. Applicant is reminded of the continuing obligation under 37 CFR 1.178(b), to timely apprise the Office of any prior or concurrent proceeding in which Patent No. 6,130,366 is or was involved. These proceedings would include interferences, reissues, reexaminations, and litigation.

Applicant is further reminded of the continuing obligation under 37 CFR 1.56, to timely apprise the Office of any information which is material to patentability of the claims under consideration in this reissue application.

These obligations rest with each individual associated with the filing and prosecution of this application for reissue. See also MPEP §§ 1404, 1442.01 and 1442.04.

2. The surrender of the original patent is acknowledged.

3. The amendments filed 5 November 2001 are objected to under 35 U.S.C. 132 because it introduces new matter into the disclosure. 35 U.S.C. 132 states that no amendment shall introduce new matter into the disclosure of the invention. The added material that is not supported by the original disclosure is as follows:

a. The amendment to Figure 4 to change the x-axis from g/ml to  $\mu$ g/ml is not supported by the originally filed parent applicant. In application 08/003885 there is nothing below the x-axis (see attached copy of the figure); thus, there is no support for the phrase "concentration in g/ml" either. The amendment of Figure 3 to change the x-axis from g/ml to  $\mu$ g/ml is supported, however, and is thus not new matter.

b. The amendment of the paragraphs beginning at column 2, line 2, to column 3, line 26, constitutes new matter, as follows:

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- i. The deletion of SEQ ID NOs of the modified  $\alpha$ -hordothionin proteins.

Without the SEQ ID NOs, it is not clear what substitutions were made. For example, column 2, lines 7-12 state that  $\alpha$ -hordothionin has 5 lysines and 5 arginines and that a high lysine derivative was made. However, without recitation of the SEQ ID NO: of the derivative, one would not know that all the arginines were substituted. Similarly, it is not clear from column 2, lines 58-62, that the derivative made was a further derivative of SEQ ID NO:5 and not just a further derivative of SEQ ID NO:4. Lastly, one would not know the “other combinations of these substitutions” that make up derivatives SEQ ID NOs:7 and 8 without recitation of the SEQ ID NOs. This deletion of information constitutes new matter because the vagueness of the statements in the specification indicates that other possibilities may have been tried.

- ii. Insertion of the phrases “however, substitution at position 12 did not work *in vivo*” and “however, substitution at position 10 did not work *in vivo*” in column 2, lines 52 and 67, respectively. The originally filed specification indicated that substitution at these positions would work. Column 2, lines 45-50, state “replacement of the cysteine at position 12 of thionin with lysine ... was found not to disrupt the 3-dimensional structure of the protein”. Column 2, lines 58-62, state “by replacement of the serine residue at position 2 with aspartic acid, the arginine at position 10 could be replaced with lysine”. An earlier paragraph indicates that functional modeling data correlates with biological activity (column 2, lines 19-22); biological activity is *in vivo* activity. Thus, addition of the phrase indicated above is new matter.

The amendment of column 3, line 30, is not new matter, but merely corrects a typographical error, as do the other amendments to the specification.

Applicant is required to cancel the new matter in the reply to this Office Action.

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4. The amendment to the figures filed 5 November 2001 does not comply with 37 CFR

1.173. Amended figures must be identified as "Amended".

5. All references and patents cited on the face of patent 5,990,389 must be cited on an information disclosure statement.

### *Claim Objections*

6. Claims 2-4, 8-9, 11-14 and 17-21 are objected to because of the following informalities:

Claims 2-3 and 19 start with an improper article, and in line 1, a comma should be inserted before "wherein".

In claim 4, line 1, there is an improper article before "protein".

In claim 8, line 1, there is an improper article before "expression" and in line 2, the comma after "7" should be deleted.

In claim 9, line 3, there is an improper article before "bacterial".

Claims 11-14 are missing an article at the start of the claim.

In claim 17, line 3, "comprising" should be replaced with --, wherein the method comprises-- and in line 4, there is an improper article before "protein".

In claim 18, line 2, --the group consisting of-- should be inserted after "from", in line 7, "comprising" should be replaced with --, wherein the method comprises-- and in line 9, there is an improper article before "protein".

In claims 20-21, line 2, "comprising" should be replaced with --, wherein the method comprises-- and there is an improper article before "protein".

***Claim Rejections - 35 USC § 112***

7. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

8. Claims 20-21 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method of enhancing the lysine content of a plant, plant cell or seed transformed with a nucleic acid encoding the protein of claim 1, does not reasonably provide enablement for a method of enhancing the lysine content of any plant, plant cell or seed. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

As currently written the claims are drawn to simply causing the protein of claim 1 to be expressed in a cell. However, the only way the specification teaches doing that is if the plant, plant cell or seed comprises a nucleic acid that encodes that protein (columns 4-6). The instant specification fails to provide guidance for a method of enhancing the lysine content of an untransformed plant, plant cell or seed.

It is suggested that the claims be amended to have an additional step prior to expression of the protein, that of transforming the plant, plant cell or seed with a nucleic acid that encodes the protein.

Given the claim breadth and lack of guidance in the specification as discussed above, the instant invention is not enabled throughout the full scope of the claims.

9. The following is a quotation of the second paragraph of 35 U.S.C. 112:

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The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

10. Claims 5-6, 15 and 20-21 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter that Applicant regards as the invention. Dependent claims are included in all rejections.

Claim 5 lacks antecedent basis for the limitation RNA sequence according to claim 4” and claim 6 lacks antecedent basis for the limitation “DNA sequence according to claim 4”, as claim 4 is drawn to a nucleotide sequence, not to an RNA or DNA sequence. It is suggested that the claims be rewritten to replace “according to claim 4” with --that encodes the protein of claim 1-- or that the claims be rewritten to claim “The nucleotide sequence of claim 4, wherein the nucleotide sequence is RNA” and “The nucleotide sequence of claim 4, wherein the nucleotide sequence is DNA”, respectively.

Claim 15 is indefinite for claiming maize cell or tissue cultures comprising sorghum, wheat or rice cells; the cells of parent claim 12 include sorghum, wheat and rice cells, as well as maize cells. It is suggested that the claim be amended to be dependent upon claim 11, and that the phrase --, wherein the cells are maize cells-- be inserted before the period.

Claim 20 is indefinite in its recitation of “causing a protein ... to be expressed in tissues of the plant” and claim 21 is indefinite in its recitation of “causing a protein ... to be expressed in the cell or seed”. It is unclear what the practitioner must do to cause the expression in a plant, plant cell or seed.

11. Claims 1-21 are free of the prior art, given the failure of the prior art to teach or suggest a protein of SEQ ID NO:1 with substitutions of lysine for one or more of the amino acids at positions 5, 11, 17, 19, 22, 30 and 41, and nucleic acids encoding those proteins.

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12. Claims 5-7, 19 and 15-16 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, second paragraph, and objections set forth in this Office action.

13. Claims 2-4, 8-9, 11-14 and 17-19 would be allowable if rewritten to overcome the objection(s) set forth in this Office action.

14. Claim 1 is allowable.

### *Conclusion*

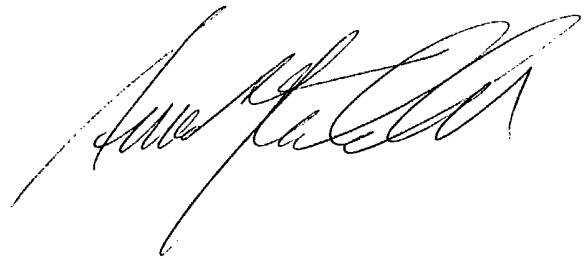
15. No claim is allowed.

16. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anne R. Kubelik, whose telephone number is (571) 272-0801. The examiner can normally be reached Monday through Friday, 8:30 am - 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson, can be reached at (571) 272-0804. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to Customer Service at (703) 308-0198.

Anne R. Kubelik, Ph.D.  
March 9, 2004



**ANNE KUBELIK  
PATENT EXAMINER**